

Appl. No. 09/869,060  
Amendment dated: November 4, 2006  
Reply to OA of: May 4, 2006

This listing of claims will replace all prior versions and listings of claims in the application.

**Listing of Claims:**

Claims 1-23(canceled).

24(currently amended). A method for assaying homocysteine in a sample, said method comprising[:] contacting said sample with two a stable aqueous reagents, said reagents together containing first reagent mixture, said first reagent mixture comprising

- a) a polyhapten having S-adenosine homocysteine (SAH) as hapten moieties thereof comprising S-adenosine homocysteine;
- b) a first enzyme, being the homocysteine converting enzyme SAH hydrolase;
- c) a primary antibody capable of binding to said polyhapten whereby to produce a complex;
- d) optionally one or more of:
  - i) adenosine or an adenosine analog,  
optionally one or more of:
    - ii) a reducing agent;  
an agent which promotes precipitation of a complex between the polyhapten and a primary antibody described below;
    - iii) a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase; and  
contacting said sample with a stable aqueous second reagent mixture, said second reagent mixture comprising  
a primary antibody capable of binding to said polyhapten whereby to produce a complex,  
a first enzyme, being the homocysteine converting enzyme SAH hydrolase;

optionally one or more of

- iv) a second antibody capable of binding to said complex;
- v) an agent which promotes precipitation of said complex;
- a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase;

~~wherein said primary antibody is capable of binding to said adenosine or adeosine analog or to a conversion product of said first or second enzymes, whereby the quantity of said complex produced is indicative of the content of homocysteine in said sample;~~

and photometrically detecting said complex[[:]].

~~wherein said reagents consist of a first reagent comprising said polyhapten, optionally said adenosine or adenosine analog, optionally said reducing agent, and optionally said agent which promotes precipitation of said complex; and a second reagent comprising said primary antibody, said first enzyme, optionally said second antibody, and optionally said agent which promotes precipitation of said complex.~~

25(currently amended). A method for assaying homocysteine in a sample, said method comprising[[:]] contacting said sample with ~~three~~ a stable aqueous reagents, ~~said reagents together containing~~ first reagent mixture, said first reagent mixture comprising

- a) a polyhapten having ~~S~~-adenosine homocysteine (SAH) as hapten moieties ~~thereof comprising S-adenosine homocysteine;~~
- b) ~~a first enzyme, being the homocysteine converting enzyme SAH hydrolase;~~
- c) ~~a primary antibody capable of binding to said polyhapten whereby to produce a complex;~~
- d) ~~optionally one or more of:~~
- i) adenosine or an adenosine analog,

optionally one or more of:

ii) a reducing agent;

an agent which promotes precipitation of a complex between  
the polyhapten and the primary antibody described below;

iii) a second enzyme capable of converting said adenosine or  
adenosine analog or a conversion product of said SAH hydrolase; and  
contacting said sample with a stable aqueous second reagent mixture, said  
second reagent mixture comprising

a primary antibody capable of binding to said polyhapten whereby to  
produce a complex,

optionally one or more of

iv) a second antibody capable of binding to said complex;

v) an agent which promotes precipitation of said complex;

a second enzyme capable of converting said adenosine or  
adenosine analog or a conversion product of said SAH hydrolase;

contacting said sample with a stable aqueous third reagent mixture, said third  
reagent mixture comprising

a first enzyme, being the homocysteine converting enzyme SAH  
hydrolase;

optionally one or more of

a second antibody capable of binding to said complex;

an agent which promotes precipitation of said complex;

a second enzyme capable of converting said adenosine or adenosine  
analog or a conversion product of said SAH hydrolase;

and photometrically detecting said complex.

~~wherein said primary antibody is capable of binding to said adenosine or~~  
~~adenosine analog or to a conversion product of said first or second enzymes,~~  
~~whereby the quantity of said complex produced is indicative of the content of~~  
~~homocysteine in said sample;~~

~~and photometrically detecting said complex;~~  
~~wherein two or three of said reagents optionally contain said agent which~~  
~~promotes precipitation of said complex, and neither of said primary antibody or said~~  
~~first enzyme is present in the same reagent as said polyhapten or said optional~~  
~~adenosine or adenosine analog.~~

26(currently amended). The method as claimed in claim 24 wherein said optional secondary antibody is present in at least one of said reagents reagent mixtures.

27(previously presented). The method as claimed in claim 24 wherein said complex is determined nephelometrically or turbidimetrically.

28(previously presented). The method as claimed in claim 24 wherein photometric determinatination takes place before complex generation is complete.

29(previously presented). The method as claimed in claim 24 wherein said sample is a serum or plasma sample.

30(currently amended). The method as claimed in claim 24 wherein at least one of said reagents reagent mixtures contains said optional agent which promotes precipitation of said complex.

31(previously presented). The method as claimed in claim 30 wherein said agent which promotes precipitation is polyethylene glycol.

32(currently amended). The method as claimed in claim 24 wherein at least one of said reagents reagent mixtures further comprises a carrier protein.

33(previously presented). The method as claimed in claim 24 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

34(previously presented). The method as claimed in claim 33 wherein said backbone structure is porcine thyroglobulin.

35(currently amended). The method as claimed in claim 24 wherein at least one of said ~~reagents~~ reagent mixtures contains said primary and secondary antibodies and additionally contains a chaotropic salt.

36(currently amended). A homocysteine assay reagent kit comprising ~~two a~~ stable aqueous ~~reagents~~, ~~said reagents together containing~~ first reagent mixture, said first reagent mixture comprising

- a) a polyhapten having ~~S-adenosine homocysteine (SAH)~~ as hapten moieties ~~thereof comprising S-adenosine homocysteine~~;
- b) ~~a first enzyme, being the homocysteine converting enzyme SAH hydrolase;~~
- c) ~~a primary antibody capable of binding to said polyhapten whereby to produce a complex;~~
- d) ~~optionally one or more of:~~
  - i) ~~adenosine or an adenosine analog,~~  
optionally one or more of:
  - ii) ~~a reducing agent;~~  
an agent which promotes precipitation of a complex between the polyhapten and the primary antibody described below;
  - iii) ~~a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase; and~~

and a stable aqueous second reagent mixture, said second reagent mixture comprising

a primary antibody capable of binding to said polyhapten whereby to produce a complex,

optionally one or more of

iv) a second antibody capable of binding to said complex;

v) an agent which promotes precipitation of said complex;

a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase.

~~wherein said primary antibody is capable of binding to said adenosine or adeosine analog or to a conversion product of said first or second enzymes, whereby the quantity of said complex produced is indicative of the content of homocysteine in said sample;~~

~~and photometrically detecting said complex;~~

~~wherein said reagents consist of a first reagent comprising said polyhapten, optionally said adenosine or adenosine analog, optionally said reducing agent, and optionally said agent which promotes precipitation of said complex; and a second reagent comprising said primary antibody, said first enzyme, optionally said second antibody, and optionally said agent which promotes precipitation of said complex.~~

37(currently amended). A homocysteine assay reagent kit comprising three a homocysteine assay reagent kit comprising a stable aqueous reagents, said reagents together containing first reagent mixture, said first reagent mixture comprising

- a) a polyhapten having S-adenosine homocysteine (SAH) as hapten moieties thereof comprising S-adenosine homocysteine;
- b) a first enzyme, being the homocysteine converting enzyme SAH hydrolase;

- c) ~~a primary antibody capable of binding to said polyhapten whereby to produce a complex;~~
- d) ~~optionally one or more of:~~
  - i) ~~adenosine or an adenosine analog,~~  
optionally one or more of:
    - ii) ~~a reducing agent;~~  
an agent which promotes precipitation of a complex between the polyhapten and the primary antibody described below;
    - iii) ~~a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase; and a stable aqueous second reagent mixture, said second reagent mixture comprising~~  
a primary antibody capable of binding to said polyhapten whereby to produce a complex,  
optionally one or more of
      - iv) ~~a second antibody capable of binding to said complex;~~  
~~an agent which promotes precipitation of said complex;~~  
a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase;  
and a stable aqueous third reagent mixture, said third reagent mixture comprising  
a first enzyme, being the homocysteine converting enzyme SAH hydrolase;
      - v) optionally one or more of  
a second antibody capable of binding to said complex;  
an agent which promotes precipitation of said complex;  
a second enzyme capable of converting said adenosine or adenosine analog or a conversion product of said SAH hydrolase.

~~wherein said primary antibody is capable of binding to said adenosine or adeosine analog or to a conversion product of said first or second enzymes, whereby the quantity of said complex produced is indicative of the content of homocysteine in said sample;~~

~~and photometrically detecting said complex;~~

~~wherein two or three of said reagents optionally contain said agent which promotes precipitation of said complex, and neither of said primary antibody or said first enzyme is present in the same reagent as said polyhapten or said optional adenosine or adenosine analog.~~

38(currently amended). The kit as claimed in claim [[35]]36 wherein said optional secondary antibody is present in at least one of said reagents reagent mixtures.

39(currently amended). The kit as claimed in claim [[35]]36, wherein at least one of said reagents reagent mixtures contains said agent which promotes precipitation of said complex.

40(currently amended). The kit as claimed in claim [[38]]39 wherein said agent which promotes precipitation is polyethylene glycol.

41(currently amended). The kit as claimed in claim [[35]]36 wherein at least one of said reagents reagent mixtures further comprises a carrier protein.

42(currently amended). The kit as claimed in claim [[35]]36 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

Appl. No. 09/869,060

Amendment dated: November 4, 2006

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43(currently amended). The kit as claimed in claim [[41]]42, wherein said backbone structure is porcine thyroglobulin.

44(currently amended). The kit as claimed in claim [[35]]36 wherein at least one of said ~~reagents~~ reagent mixtures contains said primary and said secondary antibodies and additionally contains a chaotropic salt.

45(new). The method as claimed in claim 25 wherein said optional secondary antibody is present in at least one of said reagent mixtures.

46(new). The method as claimed in claim 25 wherein said complex is determined nephelometrically or turbidimetrically.

47(new). The method as claimed in claim 25 wherein photometric determinatination takes place before complex generation is complete.

48(new). The method as claimed in claim 25 wherein said sample is a serum or plasma sample.

49(new). The method as claimed in claim 25 wherein at least one of said reagent mixtures contains said optional agent which promotes precipitation of said complex.

50(new). The method as claimed in claim 25 wherein at least one of said reagent mixtures further comprises a carrier protein.

51(new). The method as claimed in claim 25 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

Appl. No. 09/869,060

Amendment dated: November 4, 2006

Reply to OA of: May 4, 2006

52(new). The method as claimed in claim 25 wherein at least one of said reagent mixtures contains said primary and secondary antibodies and additionally contains a chaotropic salt.

53(new). The kit as claimed in claim 37 wherein said optional secondary antibody is present in at least one of said reagent mixtures.

54(new). The kit as claimed in claim 37, wherein at least one of said reagent mixtures contains said agent which promotes precipitation of said complex.

55(new). The kit as claimed in claim 37 wherein at least one of said reagent mixtures further comprises a carrier protein.

56(new). The kit as claimed in claim 37 wherein said polyhapten consists of a backbone structure onto which said hapten moieties are bound.

57(new). The kit as claimed in claim 37 wherein at least one of said reagent mixtures contains said primary and said secondary antibodies and additionally contains a chaotropic salt.